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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,993	09/01/2006	Masami Takayama	07541. 0008	7517

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EXAMINER	
COPPINS, JANET L	
ART UNIT	PAPER NUMBER
1626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,993	TAKAYAMA ET AL.	
	Examiner	Art Unit	
	Janet L. Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *13-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 19-28* is/are rejected.

7)☒ Claim(s) *24-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-28 are pending in the instant application.

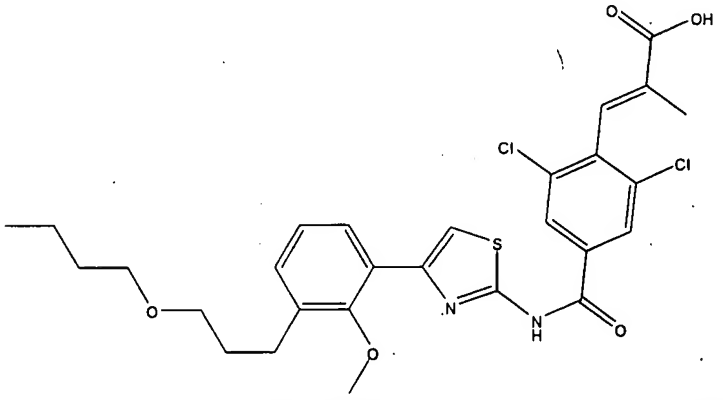
Information Disclosure Statement

2. Applicants' Information Disclosure Statement, filed February 10, 2006, has been considered by the Examiner. Please refer to the signed copy of Applicant's PTO-1449 form submitted herewith.

Election/Restrictions

3. In the Lack of Unity of October 10, 2007, Examiner Lambkin required that Applicants elect a single compound to which the claims must be restricted, in accordance with 37 CFR 1.499.

In the response of November 13, 2007, a provisional election was made **with** traverse to prosecute the compound:



(E)-3-(4-{4-[3-(3-butyloxypropyl)-2- methyloxyphenyl] thiazol-2-ylcarbamoyl}-2,6-dichlorophenyl)-2-methylacrylic acid

drawn generically to claims 1-12 and 19-25 (compounds and compositions of formula I), claim 26 (a platelet production modifier), claims 27 (its use), and claims 28 (a different method of use).

Accordingly, claims 13-18 are currently withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

As stated previously, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. Applicants traverse the finding of Lack of Unity on the grounds that the Office has not shown the absence of a significant common structural feature.

The Examiner respectfully disagrees with Applicants' traversal. Upon thorough consideration of the claims, the Examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, **Part 1(b)**, indicates that "special technical features" means those technical

features that as a whole define a contribution over the prior art.

Annex B, **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, **Part 1(e)**, indicates the permissible combinations of different categories of claims. **Part 1(e(i))** states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)** indicates the "Markush practice" of alternatives in a single claim. **Part 1(f(i))** indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, **Part 1(f)(i-iii)**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f(iv))**

indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f(v))** indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

5. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a 2-(amino-carbonyl-phenyl-acrylic acid)-4-phenyl-thiazole moiety in common, which does not define a contribution over the prior art (**variables excluded**). Attached to the instant office action is a copy of a reference that provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature' as defined in PCT Rule 13.2, by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please refer to the attached Takemoto et al EP application.

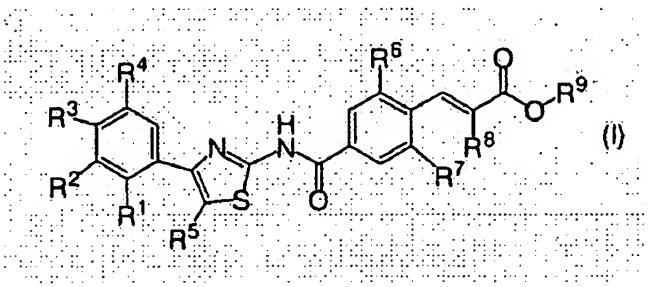
Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

Status of the Claims

6. Claims 1-28 are pending in the instant application. Claims 13-18, as previously stated, are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions. The withdrawn subject matter is patentably distinct from the elected subject matter

as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the invention of the elected subject matter is as follows:



Compounds of formula (I), depicted in claim 1, wherein R^1 and R^5 are **not** taken together to form a 5 to 8 membered ring; and the remaining variables are as defined.

As a result of the election identified above, the remaining subject matter of claims 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). The withdrawn compounds contain varying functional groups which are chemically recognized to differ in structure and function. This recognized chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. and international classification systems. Therefore the subject matter which are withdrawn from consideration as being non-elected subject matter differ materially in structure and composition and have been restricted properly and a reference that anticipates the elected compound(s) would not even render obvious the withdrawn subject matter and the fields of search are not co-extensive.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: Applicants have failed to include the structure of "general formula (I)" in claim 1. The Examiner assumes that formula I has remained unchanged, and has applied the structure of formula (I) from the original claims of February 10, 2006, for examination of the instant claims. However appropriate correction is required.

(b) Claim 25 recites a "pharmaceutical composition... which is exhibiting thrombopoietin receptor agonism." This phrase appears to be a translation from a foreign document, and it is unclear what is meant due to grammatical errors. The Examiner cautions that claim 25 appears to be drafted in terms of future intended use, and should it be amended, the claim is still directed to a product rather than a method of use. While referring to the contemplated use (i.e. "intended use") of a claimed compound is proper (thrombopoietin receptor agonist), it is not a limitation and thus of no significance in determining the patentability thereof over the prior art. Therefore claim 25 is also a duplicate of claim 24.

(c) Claim 26 recites the phrase a "platelet production modifier" in line 1, which reads on any compound, prodrug, mixture, pharmaceutical composition, agent, etc. It is unclear from the claim itself what Applicants are intending to encompass by this phrase. In the Specification on page 22, Applicants describe "platelet production modifier" as a pharmaceutical composition, therefore, the Examiner suggests replacing the term "medicament" with the term "pharmaceutical composition," which would then render the claim in compliance with 35 U.S.C. 112, second paragraph. Claim 26 is drafted in terms of a future intended use, please refer to the discussion of "intended use" in paragraph "a" of this rejection.

(d) Claim 27 provides for "the use of" a compound according to claims 1-23, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as being a reach-through claim. The claim is directed to a method of "modifiering (sic) a platelet production in a mammal," yet the claim does not meet the requirements for "how to use" under 35 U.S.C. 112, first paragraph, as stated above. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility, or a well established utility (i.e. the claim does not recite a specific disease or types of diseases that may be treated), one skilled in the art clearly would not know how to use the claimed invention. The claims are directed to a method of modifying

platelet production, yet the claim fails to present a tangible use. The Examiner suggests claiming the possible diseases and conditions that are treated (such as those discussed on page 22 of the specification), rather than claiming the mechanism, which is speculative.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 27 rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-12 and 19-25 in part rejected under 35 U.S.C. 102(b) as being anticipated by Takemoto et al, EP 1253142 A1. Takemoto et al teach 2-(aminocarbonyl-phenyl)-4-phenyl-thiazoles that are the same as the instantly claimed compounds according to formula (I), please refer to EP document page 9, formula (III), wherein "W^3" is represented by the second structure

of line 30, R^{16} is hydrogen, alkyl or halogen; R^{17}-R^{21} are hydrogen, halogen or alkyl; R^{31} and R^{32} are hydrogen, halogen or alkyl, and one of R^{31} or R^{32} is not hydrogen. Please refer to Tables 1-10 found in the EP document, for example, and specifically to RN 351434-95-2, RN 351434-96-3, and RN 351434-97-4.

Claim Objections

15. Claims 24-28 are also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Conclusion

16. In conclusion, claims 1-28 are pending in the instant application. Claims 13-18 are currently withdrawn from consideration. Claims 1-12 and 19-28 are currently rejected, and claims 24-28 are also objected to.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Coppins
January 1, 2008

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

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